Bard Access Systems, Inc.
Sherlock 3CG* Tip Confirmation System (TCS)
Traditional 510(k) Premarket Notification

MAR 19 2012

510(k) Summary
21 CFR 807.92

Sherlock 3CG* Tip Confirmation System

General Provisions	Submitter Name: Submitter Address:	Bard Access Systems, Inc. 605 North 5600 West Salt Lake City, UT 84116
	Contact Person:	Henry Boland Regulatory Affairs Specialist henry.boland@crbard.com 801.522.5000 ext. 5428 801.522.5425 fax
	Date of Preparation:	22 December 2011
Subject Device	Trade Name:	**Sherlock 3CG*** Tip Confirmation System
	Classification Name:	21 CFR 880.5970 - Class II LJS - Percutaneous, implanted, long-term intravascular catheter
Predicate Device	Trade Name:	Sapiens* Tip Confirmation System
	Classification Name:	21 CFR 880.5970 - Class II LJS - Percutaneous, implanted, long-term Intravascular catheters
	Premarket Notification:	K112744, concurrence date 20 October 2011
	Manufacturer:	Bard Access Systems, Inc.
Predicate Device	Trade Name:	Sherlock 3CG* Tip Positioning System
	Classification Name:	21 CFR 880.5970 - Class II LJS - Percutaneous, implanted, long-term Intravascular catheters
	Premarket Notification:	K091324, concurrence date 07 August 2009
	Manufacturer:	Bard Access Systems, Inc.
Device Description	The **Sherlock 3CG*** TCS is indicated for guidance and positioning of PICCs during insertion and placement. The **Sherlock 3CG*** TCS provides real-time catheter tip location information by using passive magnet tracking and the	

	patient's cardiac electrical activity (ECG). The **Sherlock 3CG*** TCS displays the location of the PICC tip using a magnetic stylet and magnetic sensors. The **Sherlock 3CG*** TCS also displays ECG waveforms received from the patient's skin (baseline ECG) and from the tip of the catheter (intravascular ECG) on the graphical user interface.
Indications for Use / Intended Use	The **Sherlock 3CG*** Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sherlock 3CG TCS provides real-time PICC tip location information by using passive magnet tracking and the patient's cardiac electrical activity (ECG). When relying on the patient's ECG signal, the Sherlock 3CG TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients. Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm PICC tip location.
Technological Characteristics	Technological characteristics of the subject **Sherlock 3CG*** TCS are equivalent with respect to the basic system design and function to that of the predicate devices, Sapiens* Tip Confirmation System and Sherlock 3CG* Tip Positioning System. Differences do not raise any new questions regarding safety and effectiveness.
Safety & Performance Tests	Verification and validation activities were designed and performed to demonstrate that the subject **Sherlock 3CG*** TCS met predetermined performance specifications. The following standards in conjunction with in-house protocols were used to determine appropriate methods for evaluating the performance of the device: IEC 60601-1:1988/1991/1995 — Medical Electrical Equipment – Part 1: General Requirements for Safety IEC 60601-1-2:2007 — Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests The subject device met all pre-determined acceptance criteria and demonstrated substantial equivalence as compared to the predicate device.
Summary of Substantial Equivalence	Based on the indications for use, technological characteristics, and safety and performance testing, the subject **Sherlock 3CG*** TCS met the minimum requirements that are considered adequate for its intended use and is substantially equivalent in design, materials, principles of operation and indications for use to the predicate devices, Sapiens* Tip Confirmation System and Sherlock 3CG* Tip Positioning System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR 19 2012

Mr. Henry Boland
Regulatory Affairs Specialist
C.R. Bard, Inc.
605 North 5600 West
Salt Lake City, Utah 84116

Re: K113808
Trade/Device Name: Sherlock 3CG™ Tip Confirmation System
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: LJS
Dated: December 22, 2011
Received: December 23, 2011

Dear Mr. Boland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113808

Indications for Use Statement

510(k) Number (if known): _____

Device Name: **Sherlock 3CG™ Tip Confirmation System**

Indications for Use:

The Sherlock 3CG™ Tip Confirmation System (TCS) is indicated for guidance and positioning of Peripherally Inserted Central Catheters (PICCs). The Sherlock 3CG TCS provides real-time PICC tip location information by using passive magnet tracking and the patient's cardiac electrical activity (ECG). When relying on the patient's ECG signal, the Sherlock 3CG TCS is indicated for use as an alternative method to chest X-ray and fluoroscopy for PICC tip placement confirmation in adult patients.

Limiting but not contraindicated situations for this technique are in patients where alterations of cardiac rhythm change the presentation of the P wave as in atrial fibrillation, atrial flutter, severe tachycardia, and pacemaker driven rhythm. In such patients, who are easily identifiable prior to catheter insertion, the use of an additional method is required to confirm PICC tip location.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113808